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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/658,736

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Alan Shluzas

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CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER

WOODALL, NICHOLAS W

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

07/20/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/658,736	Applicant(s) SHLUZAS ET AL.	
	Examiner Nicholas Woodall	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This action is in response to applicant's amendment received on June 1st, 2010.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 20-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Puno (U.S. Patent 5,360,431) in view of Mathews (U.S. Patent 6,033,406) and Foley (U.S. Patent 5,792,044) and Davison (U.S. Publication 2001/0011170).

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Puno discloses a multi-level method of treating the spine via a posterior approach comprising placing a fusion device, i.e. a bone graft, in an intervertebral disc space between a first vertebra and a second vertebra in combination with a spinal fixation system (column 8 lines 1-9), wherein the spinal fixation system includes at least one fastener in each vertebral body being immobilized by the method and an elongated member attached to the fasteners (see Figure 1). The fasteners further include a screw and U-shaped head housing that receives the head, i.e. joint, of the screw and the elongate member and the joint allows movement of the housing (see column 5 lines 47-50 and Figure 2). Puno fails to disclose the method further comprising the steps of adding a bone growth material, i.e. osteoinductive proteins or morphogenic proteins, on the fusion device, advancing a decompression tool into the surgical site to perform a decompression procedure, i.e. a laminectomy and facetectomy, on the vertebrae, and inserting an access device in a first configuration through an incision of the skin until a distal portion is located adjacent the spine, actuating the access device to a second configuration having an enlarged cross-sectional area at the distal portion spanning at least a portion of the multiple vertebrae, and performing the surgical procedures through the access device. Mathews teaches a method of treating the spine further including adding an osteogenic material to a fusion device positioned between two adjacent vertebral bodies (column 5 lines 6-11) in order to increase the amount of bone growth between the adjacent vertebral bodies. Foley teaches a method comprising the step of inserting a decompression tool into a surgical site to perform a decompression procedure on the vertebrae in order to reduce pressure on the spinal cord. Davison

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teaches a method comprising the steps of inserting an access device in a first configuration through an incision of the skin until a distal portion is located adjacent the spine, actuating the access device to a second configuration having an enlarged cross-sectional area at the distal portion spanning at least a portion of the multiple vertebrae, and performing various surgical procedures, such as decompression and fixation procedures, through the access device in order to provide a larger working area while reducing the amount of trauma experienced by the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the invention of Puno further comprising the steps of adding osteogenic material to the fusion device in view of Mathews, advancing a decompression tool into the surgical site to perform a decompression procedure on the vertebrae in view of Foley, and inserting an access device in a first configuration through an incision of the skin until a distal portion is located adjacent the spine, actuating the access device to a second configuration having an enlarged cross-sectional area at the distal portion spanning at least a portion of the multiple vertebrae, and performing the surgical procedures through the access device in view of Davison in order to increase the amount of bone growth between the adjacent vertebral bodies, to reduce pressure on the spinal cord, and to provide a larger working area while reducing the amount of trauma experienced by the patient.

Response to Arguments

4. Applicant's arguments filed June 1st, 2010 have been fully considered but they are not persuasive. The applicant's argument that the Puno reference discloses an

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open spinal procedure and cannot be modified by Davidson to be performed through an access device because Puno does not disclose the procedure being performed through an access device is not persuasive. Puno discloses a spinal fixation procedure performed without an access device. Davidson specifically teaches performing spinal procedures through an access device that provides a larger working area than previously disclosed access devices to allow the use of larger instruments and/or a plurality of instruments in an endoscopic procedure while reducing the amount of trauma experienced by the patient. The disclosure of Davidson explicitly states that the disclosed invention is not meant to be limited to use with the outlined instruments or any specific procedures as discussed by the applicant in his argument. Therefore, one having ordinary skill in the art would have found it obvious to perform the procedure of Puno or any other open surgical procedure through the access device of Davidson because the access device of Davidson is disclosed as being larger enough to allow passage of larger instruments and/or multiple instruments while reducing the amount of trauma the patient experiences. The applicant's argument that modifying the procedure of Puno to be performed through the access device as taught by Davidson would not provide predictable results is not persuasive. Under the TSM Test a claimed invention is obvious when there is a teaching, suggestion, or motivation to combine prior art teachings and has no requirement for establishing predictable results. The examiner has provided the differences between the prior art references and the claimed invention and has provided a teaching reference with a motivation for one having ordinary skill in the art to combine the prior art teachings as required by the TSM Test (MPEP 2141).

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The applicant's argument that the examiner is using hindsight is not persuasive. Any judgment on obviousness is in a sense a reconstruction based upon hindsight reasoning. However, as long as the examiner's judgment takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from the applicant's disclosure such a reconstruction is proper. In re McLaughlin, 443 F.2d 1392; 170 USPQ 209 (CCPA 1971). The examiner has not provided any new grounds of rejection making this office action **FINAL**.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
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